REMARKS

Applicants respectfully request entry of the foregoing and continued examination of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. § 1.114, and in light of the remarks which follow.

As set forth in the Advisory Action, claims 1-20 are pending. Claims 11-15 stand withdrawn. Claim 16 is amended herein to recite a nucleic acid sequence encoding the MCP-1, the protein encoded by the nucleic acid sequence of SEQ ID NO:13 or an allelic variant thereof or a sequence which is degenerate as a result of the genetic code to SEQ ID NO:13. Claims 7 and 9 are amended to depend upon claim 16. New claim 21 is added herein, as dependent upon claim 16. Basis for the amendment and new claim may be found throughout the specification as-filed, especially at page 4, second paragraph. As required by the Office, withdrawn claims 1-6, 11-15, 17, and 20 are cancelled herein without prejudice or disclaimer thereto. Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled herein.

The specification is amended to provide the sequence listing for EMBL Accession No. Y18933, as referenced in the application as-filed. Thus, no prohibited new matter is presented herein.

Claim Objections

Claims 1-10 and 16-20 stand objected to because claims 1 and 10 recite the phrase "the protein encoded by the nucleic acid sequence of EMBL Accession No. Y18933." The Office states that the accession number should also recite a sequence identifier. As suggested by the Examiner, the specification is amended

herein to add the sequence listing pursuant to 37 C.F.R. § 1.821-825 to include the sequence of the nucleic acid encoding MCP-1 and the claims are amended accordingly.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-10 and 14-21 stand rejected under 35 U.S.C. §112, first paragraph as the Office argues that the amended claims as set forth in the Amendment filed March 22, 2005 encompasses sequences different from those disclosed in the specification. Applicants traverse.

Claim 16, as amended herein, recites a nucleic acid sequence encoding the monocyte-chemoattractant-protein-1 (MCP-1), the protein encoded by the nucleic acid sequence of SEQ ID NO:13 or an allelic variant thereof, or a sequence which is degenerate as a result of the genetic code to SEQ ID NO:13. Applicants note that the MCP-1 protein itself is known, and the skilled artisan could determine allelic variants or a DNA sequence degenerate to SEQ ID NO:13 from the available amino acid sequence,or obtain other allelic mutants through hybridization performed under stringent conditions.

The present invention shows that the expression of the MCP-1 gene is dependent upon the cis-acting sequences set forth in claim 16, element (b). However, the present disclosure is not limited to the sequence of SEQ ID NO:13 (the Y 18933 clone). The skilled artisan could determine that the expression of the MCP-1 gene may have variations and deviations from SEQ ID NO:13, but which contain at least one of the cis-acting sequences of claim 16(b), as regulated by cis-acting sequences.

Further, a sequence listing setting forth the nucleic acid sequence associated with EMBL Acccession No. Y18933 is added to the specification herein. Thus, Applicants submit that the skilled artisan would be able to identify the claimed fragments and variants without undue experimentation from the sequence. Stringent conditions for hybridization are defined on page 3, line 24 to page 4, line 13 of the specification. Applicants further refer to Sambrook et al. (*Molecular Cloning, A Laboratory Manual*, 2nd edition (1989) Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY) as referenced on page 3 of the specification. Stringent conditions for hybridization are discussed in detail in this reference. However, in the interest of expediting prosecution, claim 16 is further amended herein to remove the recitation of fragments, derivatives, or variants of the sequence. The skilled artisan would be readily able to identify the claimed molecules, based on what is recited in the specification. Applicants request that this rejection be withdrawn.

Claims 1-10 and 16-20 also stand rejected under 35 U.S.C. § 112, first paragraph, because the specification purportedly does not reasonably provide enablement for a nucleic acid comprising a nucleic acid sequence encoding a protein having the biological activity of MCP-1, and 5'DHSRs or 3'DHSRs that do not explicitly comprise TGAGTCA or SEQ ID NO. 1 or SEQ ID NO. 8. Claims 1, 5, 16 and 17 also stand rejected under 35 U.S.C. § 112, first paragraph, because the specification purportedly fails to provide enablement for a nucleic acid comprising a nucleic acid sequence encoding a protein having the biological activity of MCP-1, and 5'DHSRs or 3'DHSRs that have mutations that result in DNAse I hypersensitivity, S1 hypersensitivity, or altered interaction with transcription factors.

To this end, Applicants again note that claim 16 is amended herein to remove the phrase "fragments, derivatives or allelic variants which encode a polypeptide having the biological activity of MCP-1 and an amino acid sequence identity of at least 80% to the amino acid sequence encoded by the EMBL clone Y18933". Applicants further notes that claims 5 and 17 directed to mutated hypersensitive sequences of at least 40% identity to the original sequence are cancelled herein.

Thus, Applicants submit that the number of species represented by the claimed as amended herein would be understood by the skilled artisan. Further, the Office Action states that the claims are enabled for a nucleic acid molecule comprising: (a) a nucleic acid sequence encoding MCP-1; wherein the MCP-1 protein is the protein encoded by the nucleic acid sequence of EMBL Accession No. Y18933; and (b) a 5′-DHSR or 3′-DHSR wherein said 5′-DHSR contains the nucleic acid sequence that is SEQ ID NO:4,5, or 6 and wherein said 3′-DHSR comprises the nucleic acid sequence that is TGAGTCA, or SEQ ID NO:1,2,3, or 8. In light of the above, Applicants submit that the claims are enabled and satisfy the written description requirement.

Rejections Under 35 U.S.C. § 102

Claims 1-4, 6-10, 16 and 18-20 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Genbank Accession No. aC005549 (Birren).

Birren (Genbank Accession No. AC005549) purportedly teaches a bacterial artificial chromosome (BAC) comprising a portion of chromosome 17 that comprises SEQ ID NO. 1, as well as the genomic DNA encoding the MCP-1 gene. Applicants traverse.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and M.P.E.P. § 2131. Applicants submit that Birren does not recite every element of the presently claimed invention.

As amended herein, claim 16 recites an isolated nucleic acid molecule consisting essentially of a nucleic acid molecule encoding the MCP-1 protein. Birren describes a 147 Kb nucleic acid sequence of chromosome 17. This is not the specific11,7 Kb sequence of the presently claimed molecule, as remaining independent claim 16 now recites "consisting essentially of". Birren does not even suggest the defined hypersensitive regions recited in claim 16.

Furthermore, Birren fails to recite each element of the claimed invention, because Birren fails to provide a sufficient description or guidance to reproduce the claimed nucleic acid molecule. Thus, Birren is not enabled, and cannot be cited as reciting the elements of the presently claimed invention. "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure" M.P.E.P. § 2121.01 and *In re Hoeksema,* 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003).

To this end, Birren discloses a 147 Kb portion of chromosome 17, but does not indicate or even suggest any part of the structure of the chromosome. Thus, not only is the 147 Kb nucleic acid sequence of Birren different from the about 11,7 Kb nucleic acid sequence of claim 16, but Birren fails to enable its disclosure.

Applicants respectfully request that the rejections under 35 U.S.C. § 102 be withdrawn.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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